

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**THE BENEFICIARY COMPLAINT  
PROCESS OF THE MEDICARE  
PEER REVIEW ORGANIZATIONS**



**JUNE GIBBS BROWN  
Inspector General**

**NOVEMBER 1995  
OEI-01-93-00250**

## **OFFICE OF INSPECTOR GENERAL**

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services' (HHS) programs as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by three OIG operating components: the Office of Audit Services, the Office of Investigations, and the Office of Evaluation and Inspections. The OIG also informs the Secretary of HHS of program and management problems and recommends courses to correct them.

### **OFFICE OF AUDIT SERVICES**

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

### **OFFICE OF INVESTIGATIONS**

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil money penalties. The OI also oversees State Medicaid fraud control units which investigate and prosecute fraud and patient abuse in the Medicaid program.

### **OFFICE OF EVALUATION AND INSPECTIONS**

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in these inspection reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs. This report was prepared in the Boston regional office under the direction of Mark R. Yessian, Ph.D., Regional Inspector General, and Martha B. Kvaal, Deputy Regional Inspector General. Project staff included:

#### **BOSTON**

Joyce M. Greenleaf, *Project Leader*  
Elizabeth A. Robboy

#### **HEADQUARTERS**

Barbara Tedesco, *Technical Support Staff*

To obtain a copy of this report, call the Boston Regional Office at (617) 565-1050.

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**THE BENEFICIARY COMPLAINT  
PROCESS OF THE MEDICARE  
PEER REVIEW ORGANIZATIONS**



**JUNE GIBBS BROWN  
Inspector General**

**NOVEMBER 1995  
OEI-01-93-00250**

# EXECUTIVE SUMMARY

---

## PURPOSE

The purpose of this study is to assess the beneficiary complaint process of Medicare Peer Review Organizations.

## BACKGROUND

In April 1993, the Medicare Peer Review Organizations (PROs) altered the way they ensure the necessity, quality, and appropriateness of care rendered to Medicare beneficiaries. Previously, PROs did this by addressing individual clinical problems identified primarily through reviewing random sample medical records. Now PROs aim to improve the overall practice of medicine by analyzing patterns of care and outcomes and by sharing information with the medical community. Under this approach, the PROs' random sample record reviews--already reduced from earlier levels--are being completely phased out. Thus, the PROs' process for receiving and investigating complaints from Medicare beneficiaries takes on added significance. It becomes a major vehicle through which the PROs can identify and respond to individual instances of poor medical care. It is vital, therefore, that the complaint process be functioning well.

This report is based primarily on data from surveys of 22 PROs representing 72 percent of the beneficiary population in the country and aggregate data from the Health Care Financing Administration (HCFA) reflecting all the PROs' record review workload, including complaints, during the fourth contract. Our findings are based on PROs' experiences under the fourth contract with HCFA.

## FINDINGS

*Complaints to PROs can be an important source for identifying quality-of-care problems.*

- ▶ Between 10 and 15 percent of the complaints to all 53 PROs led to confirmed quality-of-care problems.
- ▶ Half the PROs in our sample identified health systems problems through complaints.

*Medicare beneficiaries are often unaware of their opportunities to complain to PROs about the quality of their medical care.*

- ▶ Seventy-seven percent of Medicare beneficiaries did not even know about the PROs, according to a recent national OIG survey.

- ▶ Thirteen of the 22 PROs (59 percent) in our sample cited difficulties in making beneficiaries aware of the complaint process.

*As it works now, the complaint process has some flaws that undermine its effectiveness.*

- ▶ **Lack of Substantive Responses.** The Federal confidentiality regulations preclude PROs from sharing the results of their investigations with the beneficiaries without physicians' consent.
- ▶ **Few Complaints.** The PROs received too few complaints to identify patterns of poor care by individual physicians and hospitals.
- ▶ **Lengthy Process.** Beneficiaries can wait a long time for the results of the PROs' complaint investigation.

## RECOMMENDATIONS

The complaint process needs to be working well in order for HCFA to achieve its stated mission. Below we offer our recommendation in three parts, one part to address each flaw we identified. It also addresses the lack of awareness about the PROs' complaint process that we found among beneficiaries. If implemented, our recommendation would result in a complaint process that is more effective and more accountable to beneficiaries. Further, it would contribute to HCFA's mission and to goals from its strategic plan.

*The HCFA should work with PROs to identify cost-effective ways to correct the flaws in the complaint process. Toward that end, HCFA should:*

- ▶ *Require PROs to respond substantively to the complainant. The HCFA should give this the highest priority.*

A substantive response would require a PRO to describe: (1) what it did to investigate the complaint, (2) what the investigation revealed, including whether a quality-of-care problem was confirmed and, if so, the nature of the problem, and, (3) if a quality-of-care problem was confirmed, what action the PRO took based on it.

- ▶ *Identify cost-effective ways to enhance Medicare beneficiaries' awareness of PROs and the complaint process.*

The HCFA should allow PROs more flexibility in conducting their outreach activities. Such flexibility could allow PROs to survey local beneficiaries, target outreach to family members of beneficiaries as well as pre-retirement groups, and even cultivate new outreach strategies in the medical community. The HCFA should also identify benchmark practices or promising approaches to informing beneficiaries of the complaint process. The recent work of HCFA's Beneficiary Communications Steering Committee and others could contribute to this effort.

► *Streamline the complaint process.*

The HCFA should search for ways in which the process of investigating and responding to complaints could be expedited. It could benefit by examining ways in which other bodies conduct reviews for complaints about medical care. It could also identify and share promising approaches taken by individual PROs to streamline the complaint process.

## COMMENTS ON THE DRAFT REPORT

We solicited and received comments on the draft report from the Health Care Financing Administration (HCFA), the American Medical Peer Review Association (AMPRA), the American Medical Association (AMA), the American Association of Retired Persons (AARP), and the Coalition for Consumer Protection and Quality in Health Care Reform (hereafter referred to as the Coalition). We include the complete text of the detailed comments in appendix E. We also received a comment of concurrence from the Assistant Secretary for Planning and Evaluation. Below, we summarize the major comments of the respondents on our three recommendations and then, in italics, summarize our responses. In the report, we also made a number of minor technical corrections in response to respondent comments.

The HCFA took our first recommendation on substantive responses to complaints under advisement, expressing concerns about balancing such responses with the due process rights of providers. The AMPRA and the AMA expressed general support for substantive responses but also stressed the need to balance this with the due process rights of providers. The AARP and the Coalition both expressed strong support for our recommendation. *With respect to concerns raised by HCFA, AMPRA, and the AMA, we understand the difficulty of achieving a workable balance between the principles of the Health Care Quality Improvement Program and the basics of an effective complaint process. However, we maintain our commitment to the point made in our report: that without a substantive response to beneficiaries, it is not likely that HCFA can develop a complaint process that is credible to beneficiaries.*

The HCFA and the other respondents all agreed with our recommendation to enhance beneficiary awareness of the complaint process.

The HCFA expressed concern that our recommendation to streamline the complaint process might result in a less complete or conscientious review. All the other respondents agreed opportunities exist to streamline the process. *We recognize opportunities to streamline may be limited but maintain that such opportunities do exist. Thus, we suggest that HCFA reconsider this recommendation. We believe that some streamlining of the complaint process is essential to achieving a more effective process.*

# TABLE OF CONTENTS

---

	<b>PAGE</b>
<b>EXECUTIVE SUMMARY</b>	
<b>INTRODUCTION</b> .....	1
<b>FINDINGS</b>	
• Complaints Are an Important Source for Quality-of-Care Problems .....	3
• Beneficiaries Often Unaware of Their Opportunities to Complain to PROs .....	5
• Complaint Process Has Flaws .....	6
<b>RECOMMENDATIONS</b> .....	9
<b>COMMENTS ON THE DRAFT REPORT</b> .....	11
<b>APPENDICES</b>	
<b>A: Sources of Record Reviews</b> .....	A-1
<b>B: Summary of the Fee-For-Service Complaint Timeframes</b> .....	B-1
<b>C: Methodology</b> .....	C-1
<b>D: Random Sample and Complaint Review for all PROs</b> .....	D-1
<b>E: Complete Comments on the Draft Report</b> .....	E-1
<b>F: Notes</b> .....	F-1

# INTRODUCTION

---

## **PURPOSE**

The purpose of this study is to assess the Medicare Peer Review Organizations' beneficiary complaint process under the fourth contract period.

## **BACKGROUND**

### **Peer Review Organizations and the Health Care Quality Improvement Program**

In April 1993, the Medicare Peer Review Organization (PROs) began implementing their fourth contracts with the Health Care Financing Administration (HCFA). These contracts marked major changes in the PROs' aims and operations. Prior to the fourth contracts, PROs had sought to ensure the necessity, quality, and appropriateness of care rendered to Medicare beneficiaries by identifying and addressing individual clinical problems. They did this through reviewing medical records, which at times represented as much as 15 percent of Medicare hospital discharges.

Since 1993, PROs have aimed to improve the overall practice of medicine by analyzing patterns of care and outcomes and by sharing information with the medical community. The HCFA refers to this initiative as the Health Care Quality Improvement Program (HCQIP). The HCQIP rests heavily on the precepts of continuous quality improvement, which hold that it is far more important to improve the overall performance levels even slightly than it is to identify and correct poor performers at the margin. This emphasis reflects the kind of redirection called for by the Institute of Medicine in its comprehensive assessment of Medicare quality assurance efforts.<sup>1</sup>

Thus, PROs' operational responsibilities are much different than in the past. They have reviewed far fewer medical records. For at least part of the fourth contract period, the PROs have conducted record reviews on a 5 percent inpatient random sample, though by October 1995 that sample will be completely eliminated.<sup>2</sup> Appendix A displays the sources of record reviews during the early implementation of the fourth contract. The HCFA still requires the PROs to conduct record reviews in certain instances under the fourth contract. These instances include quality-related beneficiary complaints.<sup>3</sup>

### **The Complaint Process**

The Omnibus Budget Reconciliation Act of 1986 (Public Law 99-509) requires PROs to review all written, quality-related complaints received from Medicare beneficiaries.<sup>4</sup>

Once the PRO receives a quality-related beneficiary complaint in writing, it must review the appropriate medical records. The PRO manual requires that each task in investigating the complaint be completed within certain timeframes (see appendix B for a complete review of the timeframes involved). Once all reviews and re-reviews are completed, the

PRO invites the provider and/or physician to comment on the case. It also seeks consent from the physician to allow information about the case to be disclosed back to the beneficiary, as required in the confidentiality regulations.<sup>5</sup>

### **The Significance of the Beneficiary Complaint Process Under the Fourth Contract**

With less review under the fourth contract, the beneficiary complaint process has become especially important to PROs' ability to identify questionable care. The process represents a key safety valve for beneficiaries, their families, and advocates, who can register complaints against individual physicians and hospitals. The HCFA recognizes the heightened significance of the complaint process and includes it in three of the four elements it uses to define beneficiary protections.<sup>6</sup> In its vision statement describing the successful PRO in 5 years, HCFA suggests that "[PROs] will have earned a position of trust in the eyes of plans, providers, and practitioners and beneficiaries" and that this public trust will be "based on responsive investigation of complaints and protection of consumers."<sup>7</sup> Thus, it is important that the complaint process functions well.

### **METHODOLOGY**

We relied on three primary sources: (1) surveys of officials from 22 PROs, (2) aggregate data from HCFA reflecting all PROs' record review workload, and (3) a national survey of Medicare beneficiaries. The 22 PROs represent 72 percent of the beneficiary population in the country. We chose those 17 PROs in States with the largest beneficiary populations and 5 of those with the lowest beneficiary populations. (See appendix C for a more detailed discussion of our methodology.)

Our findings are based on PROs' experiences under their fourth contract with HCFA.

Hereafter, we use the term complaints to refer to those quality-related complaints made to PROs by or on behalf of beneficiaries that prompted the PROs to review medical records.

We conducted our review in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

# FINDINGS

---

*Complaints to PROs can be an important source for identifying quality-of-care problems.*

- ▶ Between 10 and 15 percent of the complaints to all 53 PROs led to confirmed quality-of-care problems. In contrast, less than 1 percent of the random sample record reviews led to such problems. Proportionally, then, complaints have been a richer source of quality-of-care problems, even though the majority of such problems have emerged from the random sample record reviews.

Data from our sample of 22 PROs confirm the value of complaints as a source of information about quality of care. Between 8 and 14 percent of complaints led those PROs to identify and confirm quality-of-care problems.<sup>8</sup> All but one PRO in our sample confirmed least one quality-of-care problem through a beneficiary complaint.<sup>9</sup>

The quality-of-care problems identified through complaints involved both physicians and hospitals. About two-thirds of all the quality-of-care problems the 53 PROs identified involved physicians and one-third, hospitals. In our sample of 22 PROs, we found about half the problems involved physicians and half, hospitals.

The importance of complaints as a source of confirmed quality problems is magnified when we consider just how few record reviews are triggered by complaints. Just 0.1 percent of all PRO record reviews were conducted due to complaints (see appendix D). Yet the quality-of-care problems stemming from those reviews accounted for 2 percent of all problems identified by the PROs under the fourth contract. As the random sample reviews continue to decrease, however, complaint reviews will constitute a larger share of the PROs' remaining review work.

- ▶ Half the PROs in our sample identified health systems problems through complaints. These systemic issues included such problems as beneficiaries being prematurely discharged from hospitals and lapses in their treatment during transfers among different care settings.

Identifying systemic causes of quality-of-care problems is clearly a focus of the PROs under their fourth contract. In our sample, 11 PROs (10 from the high-population and 1 from the low-population stratum) reported having identified 17 instances of health systems problems through their investigations of complaints. The systems problems included: four systems related to discharge planning; three to communications; two to transfers; and eight to issues such as patient restraints, protocols for pressure ulcer prevention, and lack of timely reporting of test results, among others.<sup>10</sup>

A health systems problem identified by one PRO, for example, concerned the proper placement of feeding tubes. Based on a complaint, this PRO learned that a beneficiary suffered complications due, at least in part, to being fed through a feeding tube inserted

into a lung. No protocol existed to confirm the tube's proper placement through x-ray or other imaging. The PRO alerted facilities in its area and its own reviewers to the potentially catastrophic consequences of improper tube placement.

- ▶ Sixteen of the 22 PROs (73 percent) in our sample rated the complaint process as critical to their ability to protect beneficiaries from individual instances of poor care.

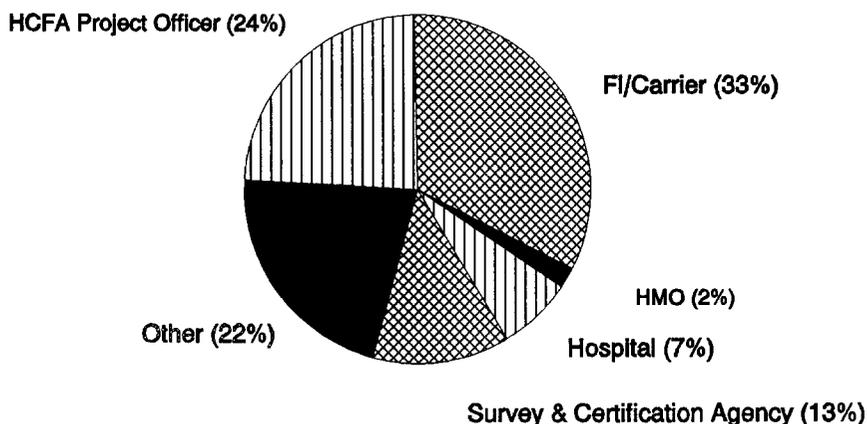
Officials from one PRO with whom we spoke pointed out that the opportunity to complain is an important safeguard to identifying problems that will no longer be caught through the random sample review. Officials from another PRO noted that identifying even one quality-of-care problem through a complaint can protect many other beneficiaries from facing the same problem. Others pointed out that the experience of complaining, could, in fact, be cathartic for beneficiaries.

The HCFA also recognizes the importance of the complaint process, as reflected in an internal memorandum on beneficiary protection:

The purpose of the beneficiary protection program is to reduce the likelihood of harm, from both systemic causes and from individual incompetent or impaired providers and practitioners. Additional protection will be afforded by addressing specific instances of poor care identified through beneficiary complaints.<sup>11</sup>

The extent to which PROs have referred complaints to other parts of the medical community, known as joint referrals, underscores the importance of their roles within those communities. The PROs make referrals when complaints raise concerns beyond the PROs' authority, such as concerns about the cleanliness of a facility or the qualifications of its staff. In our sample, 19 of the 22 PROs referred some of the complaints they investigated to others in the medical community. Overall, these PROs referred at least 17 percent and possibly as many as 29 percent of all the complaints they received.<sup>12</sup> As shown in figure 1, PROs referred the majority of complaints to fiscal intermediaries (33 percent), followed by HCFA project officers (25 percent), and survey and certification agencies (13 percent).<sup>13</sup>

**Figure 1**  
**Complaints Jointly Referred by PROs Under the Fourth Contract**



**Note:** N=560 complaints. These represent joint referrals for 19 of the 22 PROs in our sample. Complaints may be jointly referred to more than one entity.

**Source:** HHS Office of Inspector General Survey of 22 PROs, January 1995

In addition to making joint referrals to others, the PROs in our sample reported occasionally receiving referrals from members of the medical community. Most often, these referrals came from physicians, but some also came from hospitals and State medical boards. Not one PRO in our sample, however, had explicit policies to encourage referrals from either physicians, hospitals, or medical boards. While these referrals were few in number, the PRO officials described them as solid and often including specific details.<sup>14</sup>

*Medicare beneficiaries are often unaware of their opportunities to complain to PROs about the quality of their medical care.*

- ▶ Seventy-seven percent of Medicare beneficiaries did not even know about the PROs, according to a recent national OIG survey.
- ▶ Thirteen of the 22 PROs (59 percent) in our sample cited difficulties in making beneficiaries aware of the complaint process.

In accord with their contracts, the PROs in our sample have conducted outreach activities aimed at increasing beneficiaries' awareness of their rights under Medicare and of their opportunities to complain about quality to the PROs. They reported undertaking roughly the same range of outreach activities (see the box on the next page).

Twenty of the 22 PROs judged their outreach activities critical. When asked which outreach activities lead to the most complaints, PROs identified local presentations more often than any other activity.<sup>15</sup> Yet reaching beneficiaries through such presentations has presented some difficulties. In many large States, the beneficiaries are dispersed and thus difficult to reach.<sup>16</sup> Many beneficiaries are unable to attend local presentations due to frailty, weather conditions, inconvenience, or lack of knowledge about the presentations.

Successfully reaching beneficiaries not involved in local senior centers presents challenges to the PROs. Although many PROs rely in part on direct mailings to beneficiaries, some questioned their value, because beneficiaries are often inundated with reading materials. And while indications from HCFA suggest that PRO outreach activities have become an increasingly important part of the work that PROs do, resources for those activities remain limited.

### 22 PROs' Outreach Activities

Outreach Activity <sup>a</sup>	Number of PROs
Hotline Advertising	22
Newspaper Ads/Articles	22
Local Presentations	22
Flyers	21
Pamphlets/Booklets	21
Press Releases	20
Audio/Visual Aids	18
Public Service Announcements	17
Other <sup>b</sup>	16
Beneficiary Newsletters	14

<sup>a</sup> We adapted this list of outreach activities from the Citizen Advocacy Center's December 1992 survey of PROs.

<sup>b</sup> Other includes conference exhibits, training volunteers who work with beneficiaries, beneficiary liaison committees, and cable television shows, among others.

Source: Office of Inspector General survey of 22 PROs, January 1995.

*As it works now, the complaint process has some flaws that undermine its effectiveness.*

- ▶ **Lack of Substantive Responses.** The Federal confidentiality regulations preclude PROs from sharing the results of their investigations with the beneficiaries without physicians' consent. Thirteen of the 22 PROs (59 percent) in our sample judged these regulations to be a major barrier to a more effective complaint process.

The confidentiality regulations hinder the PROs' ability to be responsive to beneficiaries who complain. These regulations require the PROs to gain the consent of physicians before disclosing information to the beneficiary. Without that consent, PROs cannot reveal the results of the record reviews and must therefore respond in generalities. The box on the next page presents one PRO's response to a beneficiary complaint in which the PRO did in fact confirm a physician problem, but the physician failed to consent to disclosure. These restrictions frustrate the PROs, and, in the words of one PRO official, "leave beneficiaries feeling cheated."

When the physician does consent to disclosure, the information released by the PRO is still limited in some important ways. The response would likely exclude any PRO actions directed to the physician, such as education or referral to the hospital quality assurance committee. The box below presents part of such a response.

According to the complaint data for the 22 PROs in our sample, physicians consented to disclose information to the beneficiary 45 percent of the time.<sup>17</sup> However, when the complaint involved a confirmed physician quality-of-care problem, physicians consented 13 percent of the time. Some PROs appear more successful than others in gaining physician consent for disclosure. For example, one PRO in our sample gained physicians' consent for 90 percent of all complaints for which it requested consent and for 50 percent of the complaints involving confirmed physician problems. Thirteen of the 22 PROs in our sample reported that they had yet to gain consent for any complaint involving a confirmed physician quality-of-care problem.<sup>18</sup>

***Response to a Complaint with a Confirmed Problem But No Consent to Disclose***

*"The [PRO] has completed a review of the medical record(s) for the above-referenced services. You may be assured that the quality of care issues, if any were identified by [the PRO], will receive the appropriate corrective action. As outlined in previous correspondence to you, it is Medicare's policy to handle quality reviews regarding the physician on a confidential basis with the physician(s) involved only, unless the physician agrees to the release of our findings to you."*

***Response to a Complaint with a Confirmed Problem And Consent to Disclose***

*"This letter is written to inform you of the outcome of our review concerning care provided...As you are aware, [PRO] is responsible for reviewing patient charts in order to assure the care provided to Medicare beneficiaries meets professionally accepted standards of quality. The medical record and your letter were reviewed by two physician consultants of the appropriate specialty. The areas of concern have been addressed with both the facility and the attending physician."*

- ▶ **Few Complaints.** The PROs received too few complaints to identify patterns of poor care by individual physicians and hospitals. In fact, 9 of the PROs (41 percent) judged lack of beneficiary complaints to be a major barrier to their ability to identify quality-of-care concerns.

During our telephone interviews, PRO officials often noted that while they judge the complaint process as critical to their ability to protect beneficiaries, they lack the volume of complaints to identify patterns emerging from them. Under the HCQIP, identifying patterns is an important prerequisite to taking any action directed toward a physician or a hospital based on quality-of-care problems. With PROs receiving so few complaints, the likelihood of identifying such patterns is small. The PROs in our sample received between 8 and 164 complaints per million beneficiaries. Even when we accounted for the length of time these PROs have operated under the fourth contract, the number of complaints remained low.<sup>19</sup>

Overall, complaints have accounted for about 0.1 percent of the PROs' review caseload. The bulk of their review caseload comes from the 5 percent random sample (about 72 percent).<sup>20</sup> And the low volume of complaints coupled with the reduction in record review overall weakens the PROs' ability to identify quality-of-care problems, and thus patterns.

We noted previously that beneficiaries are often unaware of the PROs and that PROs acknowledge difficulties in reaching beneficiaries. The low volume of complaints may also be related to other factors as well. For example, half the PRO officials with whom we spoke identified beneficiaries' reluctance to file a complaint as a major barrier and nearly half as a minor barrier. These officials noted that beneficiaries fear reprisals from the medical community on which they rely and also respect. This reluctance can be exacerbated in rural areas where beneficiaries have fewer choices of where to receive their care. Another factor that may account for the low volume of complaints is that beneficiaries can complain to others, such as State medical licensure boards, ombudsmen, hospitals, or their own physicians, rather than the PROs. But how often they complain to these other entities is unknown. Nothing in the PRO manual, however, directs the PROs to encourage beneficiaries to lodge their complaints with all the possible entities.

- ▶ **Lengthy Process.** Beneficiaries can wait a long time for the results of the PROs' complaint investigation. Fifteen of the PROs (68 percent) judged the length of the process to be a major barrier to a more effective beneficiary complaint process.

The complaint process involves multiple steps, ending with the PROs' final responses to the beneficiaries who complained. Each step has a specific timeframe for completion, and these make it difficult for PROs to respond quickly (see appendix B for the complaint timeframes). If a complaint involves no confirmed quality-of-care problem, the process should last a maximum of 110 days. However, when the PRO identifies a quality-of-care problem, the process can take up to 220 days--250 if a re-review is requested. In one complaint we reviewed, which involved both a confirmed quality-of-care problem and a re-review, the beneficiary received the PRO's final response 266 days after the PRO received the complaint.

The PRO officials who cited length of the process as a major barrier reported being constrained by it. They identified with the beneficiaries' frustrations and suggested that the length could discourage beneficiaries from complaining to the PRO.

Many PRO officials with whom we spoke are trying, where possible, to streamline the process, or at least to better prepare beneficiaries for the long wait. For example, one PRO routinely combines its request for consent to disclosure with the physician's opportunity to request a re-review, thereby shaving as many as 60 days. Another PRO employs a case management approach, so that beneficiaries have a single contact person throughout the process. Other PROs inform the beneficiaries about the timeframes when they complain. Some correspond routinely with beneficiaries throughout the process.

## **RECOMMENDATIONS**

---

The complaint process needs to be working well in order for HCFA to achieve its stated mission of serving "beneficiaries effectively."<sup>21</sup> Below we offer our recommendation in three parts, one part to address each flaw we identified. It also addresses the lack of awareness about the PROs' complaint process that we found among beneficiaries. If implemented, our recommendation would result in a complaint process that is more effective and more accountable to beneficiaries. Further, it would contribute to HCFA's mission and to goals from the strategic plan that call for HCFA to "act on [program] weaknesses to assure they respond to beneficiaries' needs."<sup>22</sup>

*The HCFA should work with PROs to identify cost-effective ways to correct the flaws in the complaint process. Toward that end, HCFA should:*

- ▶ *Require PROs to respond substantively to the complainant. The HCFA should give this the highest priority.*

A substantive response would require a PRO to describe: (1) what it did to investigate the complaint, (2) what the investigation revealed, including whether a quality-of-care problem was confirmed and, if so, the nature of the problem, and, (3) if a quality-of-care problem was confirmed, what action the PRO took based on it.

Many physicians and hospitals are likely to have concerns about providing such feedback to those who have complained to the PROs. But at a time of increasing consumer involvement in patient-care decisions, beneficiaries (and their families) are unlikely to have confidence in a process that fails to afford them substantive feedback on how the PROs responded to their complaints.

To facilitate substantive responses, HCFA could amend the PRO regulations to eliminate the requirement that physicians consent to disclosure before providing feedback to complainants. It has been considering such a revision for some time. Another, more expeditious approach would be for HCFA to issue contract modifications or manual instructions calling for substantive responses to complainants. This approach would require an interpretation that a regulatory amendment is unnecessary because of HCFA's existing statutory authority that allows disclosure "to the extent that may be necessary to carry out the purposes of" the PRO program.

- ▶ *Identify cost-effective ways to enhance Medicare beneficiaries' awareness of PROs and the complaint process.*

The HCFA should allow PROs more flexibility in conducting their outreach activities. Such flexibility could allow PROs to survey local beneficiaries, target outreach to family members of beneficiaries as well as pre-retirement groups, and even cultivate new outreach strategies in the medical community. Any efforts in this realm could tie in closely with HCFA's consumer information strategy.

The HCFA should also identify benchmark practices or promising approaches to informing beneficiaries of the complaint process. The recent work of HCFA's Beneficiary Communications Steering Committee, the Communications Network sponsored by the American Medical Peer Review Association, and the Citizen Advocacy Center could all contribute to this effort.

▶ *Streamline the complaint process.*

The HCFA should search for ways in which the process of investigating and responding to complaints could be expedited. It could benefit by examining ways in which other bodies conduct reviews for complaints about medical care. It could also identify and share promising approaches taken by individual PROs to streamline the complaint process. A benchmarking effort of this kind would be in concert with the PROs' overall emphasis on continuous quality improvement.

# COMMENTS ON THE DRAFT REPORT

We solicited and received comments on the draft report from the Health Care Financing Administration (HCFA), the American Medical Peer Review Association (AMPRA), the American Medical Association (AMA), the American Association of Retired Persons (AARP), and the Coalition for Consumer Protection and Quality in Health Care Reform (hereafter referred to as the Coalition). We include the complete text of the detailed comments in appendix E. We also received a comment of concurrence from the Assistant Secretary for Planning and Evaluation. Below, we summarize the major comments of the respondents on our three recommendations and then, in italics, offer our responses. In the report, we made a number of minor technical corrections in response to respondent comments.

## RECOMMENDATIONS FROM THE DRAFT REPORT

*The HCFA should work with the PROs to identify cost-effective ways to correct the flaws in the complaint process. Toward that end, HCFA should:*

- ▶ *Require the PROs to respond substantively to the complainant. This is the standard to which the Joint Commission on the Accreditation of Health Care Organizations holds hospitals accountable. The HCFA should give this the highest priority.*

The HCFA took this recommendation under advisement, expressing concerns about balancing such responses with the due process rights of providers. The AMPRA and the AMA expressed general support for substantive responses but also stressed the need to balance this with the due process rights of providers. The AMA specified in detail the due process elements that it favors and expressed a preference for a regulatory approach to any changes in the physician disclosure process. The AMPRA questioned the accuracy of our reference to a standard from the Joint Commission on the Accreditation of Health Care Organizations. The AARP and the Coalition both expressed strong support for our recommendation. The AARP favored implementing the recommendation through contract modifications rather than through regulation. The Coalition expressed frustration with the lack of meaningful responses and questioned the PROs' ability to represent Medicare beneficiaries without a much improved complaint process.

*With respect to concerns raised by HCFA, AMPRA, and the AMA, we understand the difficulty of achieving a workable balance between the principles of the Health Care Quality Improvement Program and the basics of an effective complaint process. However, we maintain our commitment to the point made in our report: that without a substantive response to beneficiaries, it is not likely that HCFA can develop a complaint process that is credible to beneficiaries.*

*We appreciate AMPRA pointing out the out-of-date standard from the Joint Commission, and we dropped the reference from the recommendation. The Commission's 1996 manual*

*calls for the resolution of complaints and recognizes the rights of patients to include "unrestricted access to communication."*

- ▶ ***Identify cost-effective ways to enhance Medicare beneficiaries' awareness of PROs and the complaint process.***

The HCFA and the other respondents all agreed with this recommendation.

*While we welcome the widespread support for this recommendation, we stress that increased beneficiary outreach sends a mixed message if it is not accompanied by reforms that lead to more substantive responses to complaints. Increased outreach is likely to raise beneficiaries' expectations regarding complaint resolution. Those expectations could be largely unmet without addressing our first recommendation.*

- ▶ ***Streamline the complaint process.***

The HCFA expressed concern that streamlining the complaint process might result in a less complete or conscientious review. It suggested that beneficiaries be made aware of the timeframes involved rather than streamlining the process. All the other respondents agreed opportunities exist to streamline the process. The AMPRA and the AMA suggested some steps of the review process can be performed concurrently, thereby streamlining the process.

*We recognize opportunities to streamline may be limited but maintain that such opportunities do exist. Thus, we suggest that HCFA reconsider this recommendation. We believe that some streamlining of the complaint process is essential to achieving a more effective process.*

# APPENDIX A

## SOURCES OF RECORD REVIEWS DURING THE EARLY IMPLEMENTATION OF THE FOURTH CONTRACT (FOR REVIEWS COMPLETED THROUGH JUNE 30, 1994)

Source of Record Being Reviewed	Number (Percent) of Inpatient Record Reviews
Random Sample Record Reviews	381,875 (72.3%)
Mandatory Reviews, including complaints <sup>a</sup>	44,575 (8.4%)
Miscellaneous Reviews <sup>b</sup>	101,681 (19.2%)
<b>TOTAL</b>	<b>528,541<sup>c</sup> (100%)</b>

**NOTES:** N=53 PROs.

<sup>a</sup> PRO mandated reviews include beneficiary complaints and records flagged for the following reasons: assistant at cataract surgery, Medicare code editor, hospital adjustment, referral from the fiscal intermediary or regional office, and hospital-issued notices of noncoverage.

<sup>b</sup> Includes records selected for the following reasons: specialty hospital, DRG 468, day and cost outliers, uniform clinical data set and cooperative cardiovascular project, focussed review selection, intervening care, fiscal intermediary prepayment reject, intensified review, ventilator-dependent unit, deemed admission, and other.

<sup>c</sup> Frequency missing=410.

**SOURCE:** HCFA PROD3 database.

**ANALYSIS:** HHS Office of Inspector General.

## APPENDIX B

### SUMMARY OF THE FEE-FOR-SERVICE COMPLAINT REVIEW TIMEFRAMES

	Number of Days	Cumulative Days
Acknowledge complaint	15	15
Receive medical records	30*	45
Complete Review	30	75
<b>If no quality concern:</b>		
Seek physician consent and provider/physician comments; and provide notice required by 476.132(a)(2)	30	105
Respond to complainant	5	110
<b>If potential quality concern:</b>		
Provide opportunity for discussion	30	105
Confirm/resolve quality concern	20	125
Provide opportunity for re-review	60	185
<b>If re-review not requested:</b>		
Seek physician consent and provider/physician comments; and provide notice required by 476.132(a)(2)	30	215
Respond to complainant	5	220
<b>If re-review requested:</b>		
Resolve/confirm quality concern	30	215
Seek physician consent and provider/physician comments; and provide notice required by 476.132(a)(2)	30	245
Respond to complainant	5	250
* If documentation is incomplete or illegible, allow an additional 15 days for submission of requested information.		
Source: HCFA, Peer Review Organization Manual, p. 537.		

# APPENDIX C

---

## METHODOLOGY

We collected the data presented in this report primarily through telephone interviews and mail surveys of 22 PROs. We chose these PROs through a stratified sample in which we arrayed PROs according to the number of Medicare beneficiaries in each State (high and low beneficiary population). We chose all 17 of the PROs for States in the high-population stratum<sup>1</sup> and a random sample of 5 PROs for States in the low-population stratum.<sup>2</sup> The PROs in our sample represent 72 percent of the Medicare beneficiary population in the country. The response rate for both the telephone interviews and the mail survey was 100 percent.

We sent out a mail survey in which we asked PROs for specific data under the fourth contract. The data included how many complaints triggered a record review, how often physicians consented to disclosure for both confirmed and non-confirmed problems, cases that were referred elsewhere, and sources for confirmed quality-of-care problems.

We supplemented the mail survey with more in-depth telephone interviews. For the interviews, we designed and pretested a discussion guide with questions about identifying quality-of-care problems, the complaint process, outreach activities, barriers to identifying individual quality-of-care problems, and barriers to establishing a more effective beneficiary complaint process, among others.

We also drew on data from HCFA's PROD3 data base (which includes the results of all inpatient record reviews) and PROD5 data base (which includes the results of all physician reviews). Through these we obtained data on the number and sources of confirmed physician and hospital quality-of-care problems for all PROs for reviews completed under the fourth contract through June 30, 1994.<sup>3</sup> Our tests of the data revealed that 10 PROs reported no beneficiary complaints when, in fact, they had received such complaints.

---

<sup>1</sup> These included the following States (listed in descending order of beneficiary population): California, New York, Florida, Pennsylvania, Texas, Ohio, Illinois, Michigan, New Jersey, North Carolina, Massachusetts, Missouri, Indiana, Georgia, Virginia, Wisconsin, and Tennessee.

<sup>2</sup> These included the following States (listed in descending order of beneficiary population): New Mexico, Utah, Montana, South Dakota, and Delaware.

<sup>3</sup> In analyzing our data on complaints and confirmed quality-of-care problems, we report the most conservative interpretations. We chose this approach to avoid double counting complaints that resulted in confirmed problems with both a physician and a hospital.

Nevertheless, when these data are viewed in the context of our telephone interviews and survey data, we believe the findings and recommendations in this report are valid.

We also relied on data from a beneficiary survey conducted by the Office of Inspector General (OIG) in the summer of 1994. The question relevant to our study sought to determine the level of beneficiaries' awareness of PROs. The OIG mailed this survey to a randomly selected national sample of 1,299 Medicare beneficiaries, of which 20 were either nondeliverable or mailed to beneficiaries who had died. A total of 1,002 beneficiaries returned completed surveys, a response rate of 78 percent. The survey results presented in this report have a margin of error of 3.5 percent at the 95 percent confidence level.

To strengthen our understanding of the complaint process, we reviewed the PRO manual and statutory and regulatory requirements concerning the complaint authority, confidentiality, and disclosure.

# APPENDIX D

**RANDOM SAMPLE AND COMPLAINT REVIEW FOR ALL PROS  
UNDER THE FOURTH CONTRACT  
FOR INPATIENT RECORD REVIEWS COMPLETED THROUGH JUNE 30, 1994**

Source of Records Being Reviewed	Number of Record Reviews	Number of Records with a Confirmed Quality Problem Involving a Physician and/or Hospital	Percentage of Records with a Confirmed Problem Concern
Random Sample Record Review	381,875 (72.3%)	4,255 (70.9%)	0.7% to 1.1%
Beneficiary Complaints	737 (0.1%)	108 (1.8%)	9.8% to 14.7%
<p><b>NOTE:</b> N=53 PROs. The number of beneficiary complaints represented here should be considered conservative because of reporting flaws. Ten PROs reported no beneficiary complaints when in fact they received such complaints under the fourth contract.</p> <p><b>SOURCE:</b> HCFA PROD3 and PROD5 data bases. <b>ANALYSIS:</b> HHS Office of Inspector General.</p>			

# **APPENDIX E**

---

## **COMMENTS ON THE DRAFT REPORT**

In this appendix, we present in full the comments from the Health Care Financing Administration, the American Medical Peer Review Association, the American Medical Association, the American Association for Retired Persons, and the Coalition for Consumer Protection and Quality in Health Care Reform. In addition to receiving comments from the groups listed, we also received a comment of concurrence from the Assistant Secretary for Planning and Evaluation.



DATE: SEP 1 1995

TO: June Gibbs Brown  
Inspector General

FROM: Bruce C. Vladeck  
Administrator *Bruce Vladeck*

SUBJECT: Office of Inspector General Draft Report: "Beneficiary Complaint Process of the Medicare Peer Review Organizations (PROs)" (OEI-01-93-00250)

We reviewed the above-referenced report which assesses the beneficiary complaint process of Medicare PROs. Attached are our comments on the report findings.

Thank you for the opportunity to review and comment on this report.

Attachment

Comments of the Health Care Financing Administration (HCFA)  
on Office of Inspector General (OIG) Draft Report:  
Beneficiary Complaint Process of the Medicare Peer Review Organizations (PROs)  
(OEI-01-93-00250)

OIG Recommendation 1

HCFA should work with PROs to identify cost-effective ways to correct the flaws in the complaint process. Toward that end, HCFA should: require PROs to respond substantively to the complainant. This is the standard to which the Joint Commission on the Accreditation of Health Care Organizations holds hospitals accountable. HCFA should give this the highest priority.

HCFA Response

HCFA will take this recommendation under advisement and further analyze its options. Physician consent is a complex and sensitive issue, entailing the balancing of physician due process and privacy interests with the need for meaningful feedback to beneficiaries..

We are also sensitive to the issue of full disclosure to the beneficiaries as it may impede the cooperative exchange of information between physician and PRO which enhances the peer review process. A provider and/or practitioner might be far willing to less volunteer of information which might directly or indirectly place them in jeopardy of civil malpractice actions.

OIG Recommendation 2

HCFA should identify cost-effective ways to enhance Medicare beneficiaries' awareness of PROs and the complaint process.

HCFA Response

HCFA concurs. Our Office of Beneficiary Services and Health Standards and Quality Bureau will work together on beneficiary outreach activities which will enhance beneficiary awareness of the complaint process. The beneficiary complaint process is an important and complex issue, affecting beneficiaries, providers, physicians, and managed care plans. We intend to meet with representatives of beneficiary, provider, physician, and managed care organizations in developing a regulation that will improve this process.

Page 2

In addition to regulatory changes, it will be necessary for our outreach program to help beneficiaries understand that an effective peer review process may limit full disclosure. We will consider the complainant's right to have information about himself/herself, and the plan's, provider's, and practitioner's rights to accurate information, while maintaining personal privacy, to ensure a balanced approach.

### Recommendation 3

HCFA should streamline the complaint process.

### HCFA Response

We are concerned that attempts to expedite the process may actually result in less than complete or conscientious review. The timeframes were established to allow adequate time for all parties to consider and take appropriate action including, where necessary, dialogue. We, therefore, are concerned about shortening the process, particularly in the way cited in the report.

Rather than shortening the process, we would suggest making the beneficiary aware of the timeframes and the necessity of the length of the process as part of an improved information process.

In revising the PRO process, HCFA and the OIG could examine the End Stage Renal Disease Network Grievance/Complaint policy which apparently works well.

### Additional Comments

We are concerned about another aspect of the complaint process which has not been addressed in the OIG report. We are concerned that current policy may not eliminate barriers for minority and disabled beneficiaries. There should be studies to determine whether complaints filed with PROs are submitted at at least the same rate from minority and disabled beneficiaries as from the general Medicare population. The HCFA strategic plan requires us to focus attention on eliminating barriers to special needs populations.

Revised:ES:PLB:PSimons for Meta Thomas

Typist:CCook:x65225

Disk:WPTThomas2:complain.wpd



AMERICAN MEDICAL PEER REVIEW ASSOCIATION

1140 Connecticut Avenue, NW • Suite 1050 • Washington, D.C. 20036 • 202/331-5790 • FAX: (202) 833-2047

September 8, 1995

June Gibbs Brown  
Inspector General  
Department of Health & Human Services  
Office of Inspector General  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Ms. Brown:

On behalf of the American Medical Peer Review Organization (AMPRA) -- the trade association representing the nation's network of peer review organizations -- I appreciate the opportunity to review the draft inspection report, *"The Beneficiary Complaint Process of the Medicare Peer Review Organizations."*

While AMPRA generally agrees with the philosophy of the report, we offer specific comments and suggestions on the matters described below:

*Require PROs to respond substantively to the complainant. This is the standard to which the Joint Commission on the Accreditation of Healthcare Organizations holds hospitals accountable. The HCFA should give this the highest priority.*

Responding substantively to a complaint has always been a delicate and complex issue for the PRO community and indeed all who engage in medical peer review. While we all sympathize with the beneficiary who wants to be fully informed about the results of the investigation of his complaint, such disclosure has serious ramifications for the conduct of peer review. Any new approach needs to be considered thoughtfully and carefully before a decision is made. Therefore, we recommend that changes be made thorough the regulatory process.

First, AMPRA supports the need to provide beneficiaries and their families with substantive feedback while maintaining the due process provisions currently in place for handling quality concerns, i.e., an appeals process. In addition, the response from the physician on the PRO findings could be forwarded to the beneficiary concurrently with the PRO's report. Finally, if full disclosure is implemented, AMPRA recommends expansion of existing immunity protection for PROs from civil suits.

While full disclosure is advocated for the beneficiary, such a decision could harm the provider relationships which PROs have formed as part of the Health Care Quality Improvement Program (HCQIP). A concerted effort would have to be made to increase the awareness and support of the providers, physicians, and plans in regard to this

matter. AMPRA would welcome the opportunity to participate in any discussions to seek an improved process.

Finally, to our knowledge, the Joint Commission does not have a standard which holds hospitals accountable to respond substantively to complaints about quality of care issues in the manner which this report recommends.

*Identify cost-effective ways to enhance beneficiaries' awareness of PROs and the complaint process.*

As has been pointed out in previous studies conducted by the Office of the Inspector General (OIG), there exists a lot of room for improvement in the ways beneficiaries are made aware of their rights. HCFA is currently working with the PROs on this topic, and PROs would welcome additional opportunities for flexibility in their outreach activities. AMPRA would be pleased to be to be part of such efforts.

*Streamline the complaint process.*

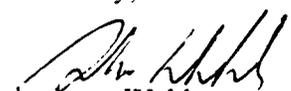
AMPRA agrees that there are many efficiencies and economies which can be built into the complaint process to afford a speedy response to the beneficiary. Potential change could simply be the by-product of a revised disclosure policy. For example, if physicians were made aware of the full disclosure requirement in the initial correspondence to them, the response time frames to the beneficiary could effectively be shortened by 30 days.

AMPRA would also like to point out that, while the random sample review has been eliminated, the improvement efforts initiated through HCQIP projects have the potential for greater impact by improving care and protecting beneficiaries on a broader scale than does review of an individual case.

AMPRA recommends that the Health Care Financing Administration (HCFA) form an improvement team to address the aforementioned issues and increase the effectiveness of the beneficiary complaint process. The improvement team -- at a minimum -- should consist of the following representatives: AMPRA; PRO leadership and applicable personnel; malpractice/legal expert; members of applicable trade associations (i.e., AMA, AHA, AARP, JCAHO, GHAA/AMCRA, etc.), HCFA, and OIG.

Again, we thank you for allowing us the opportunity to comment. Please feel free to contact me at 202/331-5790 should you have any questions.

Sincerely,

  
Andrew Webber  
Executive Vice President

# American Medical Association

Physicians dedicated to the health of America



**James S. Todd, MD**  
Executive Vice President

515 North State Street  
Chicago, Illinois 60610

312 464-5000  
312 464-4184 Fax

September 11, 1995

June Gibbs Brown  
Inspector General  
Department of Health and Human Services  
330 Independence Avenue, S.W., Rm. 5250  
Washington, D.C. 20201

Dear Ms. Brown:

The American Medical Association (AMA) greatly appreciates the opportunity to respond to the recommendations contained in the Office of Inspector General (OIG) report, The Beneficiary Complaint Process of the Medicare Peer Review Organizations. We believe that it is essential for patients to have an opportunity to express their concerns about the quality of care they receive from any provider of health care services, and that when problems of quality are identified they are addressed and corrected. However, just as the rights of patients must be observed and protected, so must we protect the rights of physicians and other providers of medical care.

The resolution of concerns raised by patients should be done in a fair and equitable manner that protects the rights of privacy and confidentiality of those being investigated. While the AMA agrees that, if possible, the complaint process should be streamlined, it must not be at the expense of denying full due process to the provider whose services are being examined. Only after affording the physician his or her full due process rights should the patient be provided a substantive response to his or her complaint.

The PRO Fourth Scope of Work correctly and appropriately attempts to improve the overall practice of medicine by analyzing patterns of care and outcomes and by sharing information with the medical community while moving away from the prior punitive approach. We are pleased that the new Fifth Scope of Work, which will provide the future direction for the PRO program, continues to emphasize cooperation and education for those providing medical care. It would be a serious mistake for the PRO program to revert to a more punitive approach (as suggested by the OIG) in an attempt to change behavior by setting aside the rights of the individual physician through eliminating the physician's consent to disclosure.

The AMA has no objections to a PRO describing what it did to investigate a complaint, what the investigation revealed (including whether a quality-of-care problem was confirmed), and what action the PRO took based on the complaint, **but** not until the provider of services has been afforded a full opportunity for due process. We believe, however, that any change in current physician disclosure regulations must be accomplished through the usual notice and comment process rather than by way of contract changes or manual instruction changes. Moreover, as it considers changes, HHS must take great care not to undercut the educational, non-punitive approach of the current PRO program, as well as the improving cooperative relationship between PROs and the medical community.

The AMA believes that prior to notifying the patient of the outcome of a PRO investigation following a complaint about quality, the physician's due process rights should be exhausted. Elements of that process should include:

- a written statement of the charges/complaint against him or her;
- adequate notice of the right to a hearing, his or her rights in the hearing, and a reasonable opportunity to prepare for the hearing;
- detailed disclosure of the evidence and witnesses against him or her sufficiently in advance of the hearing to enable preparation of the defense;
- a fair, objective, and independent hearing, with the right to ask questions of the panel members and of any hearing officer designed to reveal bias or prejudice, and the right to challenge the impartiality of any member or hearing officer;
- the right to be represented by an attorney or other person of the physician's choice;
- the opportunity to be present at the hearing and to hear all of the evidence against him or her;
- the opportunity to present a defense to the charges, including, but not limited to, the right to call, examine and cross-examine witnesses;
- a presumption of innocence and an assurance that the hearing body shall not render a decision against the physician unless the evidence produced at the hearing clearly supports that adverse determination;
- a hearing within a reasonable proximity of the location of the physician's practice; and
- a hearing which protects the interests of the physician's patients, and the public in quality patient care.

The AMA is also concerned about the possibility of well-meaning but erroneous referrals to the PRO as a result of patient complaints. With a lack of understanding as to what does and does not constitute poor quality care, there is a significant possibility that a patient's genuine concerns may lead to a referral to the PRO for care which does not reflect a quality problem at all, and which in fact is entirely appropriate. Adhering to proper due process provisions assures that no information is communicated to the patient until the physician has had the opportunity for a full and open hearing on the nature of the complaint.

We believe that HCFA should be as interested in protecting the due process rights of individual physicians as they are in providing substantive follow-up to individual patients. The AMA would welcome the opportunity to work with HCFA and the patient community in reviewing and commenting in advance on the proposed contents of any letter sent to the patient by the PRO about the quality of a physician's services. It is important that all communications with the patient regarding the complaint be handled in a nonbiased and nonprejudicial manner to protect the rights of the physician while the case is being investigated.

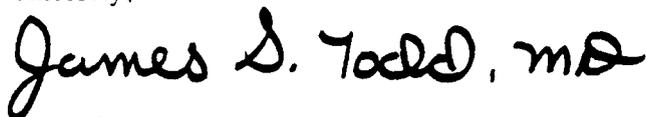
We concur with the OIG that a lack of a timely response to a patient's complaint may serve as a deterrent to a patient's willingness to refer complaints to the PRO program. We believe that it may be possible to find more efficiency in the review process by performing some steps of the review process concurrently, but the program must not compromise the physician's opportunity for due process in pursuit of more timely reviews.

Physicians have had, in large part, a positive reaction to quality review process enumerated in the PRO Fourth Scope of Work. The AMA is pleased that HCFA incorporated many of our recommendations for improving the quality review mechanisms of the PRO program. As I indicated earlier, we believe the Fifth Scope of Work builds on the positive changes of the Fourth by increasing the level of collaboration among PROs, hospitals, and physicians on quality improvement efforts. The emphasis on internal quality improvement which uses pattern analysis is to be commended, rather than a punitive approach that addressed individual clinical errors.

The AMA strongly believes that physicians must continue to play an active role in any public or private sector effort to develop national medical quality and performance standards. And that when individual problems of quality are identified, they must and will be addressed but, it must be done in a way that respects and enforces patient and physician confidentiality and without abridging the due process rights of individuals.

Once again, I want to express my appreciation for the opportunity we have had to comment on this process. The AMA wants to continue to play an active role to ensure that physicians' perspectives are part of the PRO process.

Sincerely,

A handwritten signature in black ink that reads "James S. Todd, MD". The signature is written in a cursive, slightly slanted style.

James S. Todd, MD



*Bringing lifetimes of experience and leadership to serve all generations.*

September 27, 1995

June Gibbs Brown  
Inspector General  
Department of Health & Human Services  
Office of the Inspector General  
330 Independence Ave., S.W.  
Washington, D.C. 20201

Dear Inspector General Brown:

Horace Deets has asked me to respond to your request for comments on the draft report, "The Beneficiary Complaint Process of the Medicare Peer Review Organizations." We appreciate the opportunity to comment. AARP has long supported the effective implementation of the PROs' complaint authority, and believes that your report is a great service to the beneficiary community. It is useful to be reminded of the Congressional mandate regarding PRO consideration of beneficiary complaints:

"The organization shall conduct an appropriate review of all written complaints about the quality of services ..... not meeting professionally recognized standards of health care.... The organization shall inform the individual of the organization's final disposition of the complaint."

In light of the elimination of random sample record review by the PROs, the process of investigating and responding to beneficiary complaints assumes even greater importance as a means of protecting beneficiaries from poor quality care.

Our specific comments follow. We welcome the report's recommendations, and offer suggestions for some additional ones. We also raise a few questions of clarification about the report's findings.

#### **Comments on the Recommendations**

- **Require PROs to respond substantively to the complainant**

The OIG recommends that HCFA either: (1) amend the PRO regulations to eliminate the requirement that physicians consent to disclosure before providing feedback to compliants; or (2) issue contract modifications or manual instructions calling for

Inspector General Brown

Page 2

substantive responses to complainants. We support both recommendations, both of which are consistent with AARP policy, but feel that the latter approach would be most expeditious.

We have long believed that the confidentiality regulations have a chilling effect on the beneficiary complaint process: The fact that beneficiaries have no assurance that they will ever receive a substantive response to their complaint cannot help but serve as a deterrent to registering one. Those beneficiaries who do voice complaints, and whose physicians then refuse to consent to disclosure -- which happens in 87 percent of cases when there is a confirmed quality problem -- likely feel frustrated or even angry at the lack of meaningful response. Such a situation serves to undermine overall beneficiary confidence in the PRO program.

While we recognize that many physicians and hospitals have serious concerns about changing the confidentiality regulations, the finding that over half (59 percent) of the PROs surveyed viewed these regulations as a major barrier to a more effective complaint process is compelling evidence that the regulations bear revision. In addition, the report notes that at least one PRO has been successful in gaining physicians' consent in a majority of cases, even when the complaint involved a confirmed quality problem. It would be a valuable addition to your final draft to indicate any specific methods used by that PRO. This finding suggests that, if regulations are revised, PROs will be able to respond substantively (e.g., according to the OIG's definition of what constitutes a substantive response) without alienating the physician community.

In order to help allay fears among the provider community that these responses will be used unfairly against them, we suggest:

- permitting physician responses to PRO findings to be attached as part of the PRO response to the beneficiary. This practice would parallel that used by HCFA in attaching voluntary hospital comments when it released the hospital mortality data.
- developing a recommended response letter that informs the beneficiary of the final disposition of the complaint without becoming tantamount to a verdict in malpractice litigation.

We also urge that proven quality of care findings be referred to other oversight entities as required by Memoranda of Understanding entered into by PROs in the Fifth Scope of Work.

- **Identify cost-effective ways to enhance Medicare beneficiaries' awareness of PROs and the complaint process.**

We strongly support this recommendation, which is consonant with AARP policy calling upon HCFA and the PROs to actively encourage beneficiaries to use the PROs' authority to investigate quality of care complaints. The extremely low volume of complaints (between 8 and 164 per one million beneficiaries), coupled with the elimination of random case review, jeopardizes the PROs' ability to identify quality of care problems. We agree that HCFA should give PROs more flexibility in conducting their outreach activities, including permitting them to survey local beneficiaries and targeting outreach to family members of beneficiaries as well as pre-retirees. We would like to offer any assistance that AARP may be able to provide in this effort. We further believe that the PROs' budgets should be increased to permit concerted outreach efforts.

The fact that only 23 percent of beneficiaries surveyed were aware of the existence of PROs is, of course, a major barrier to the complaint process. We are curious if the beneficiary survey revealed any other barriers. Were respondents asked if they would be willing to lodge a complaint, or if they would be reluctant to do so, and the like? Any data bearing on this issue from the beneficiary survey should be reported.

- **Streamline the complaint process.**

The current timeline for PRO review and response to beneficiaries, as outlined in the PRO manual, is far too long. For example, the process can take up to 250 days to respond to identified quality concerns in cases requiring a re-review. Over two-thirds of the PROs surveyed (68 percent) felt constrained by this lengthy process. Moreover, it is quite feasible that beneficiaries who are seriously ill may no longer be alive by the time the review is completed.

We support the OIG's recommendation to HCFA to find ways to expedite the process, e.g., by examining ways other bodies conduct complaint reviews and identifying and sharing promising approaches taken by individual PROs. For example, all PROs should be encouraged to use a case management approach, as is being used with one PRO, and to regularly communicate with beneficiaries throughout the process.

### Comments on Findings

Page 1. The text states that OBRA-86 requires PROs to review all written, quality-related complaints received from Medicare beneficiaries. However, the footnote to which this statement refers (# 4 in Appendix E) does not list physician offices as one of the settings for which PRO review is mandatory. This should be clarified.

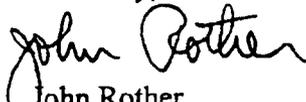
Page 3. We suggest adding an Appendix which lists the total number of beneficiary complaints received, and gives more descriptive information about the nature of the complaints reviewed, especially those that resulted in confirmed quality problems. For example, the report states that about two-thirds of these problems involved physicians, and about one-third hospitals. Were quality of care problems found in any other settings, e.g., in home health or HMOs? Such information would provide more context for interpreting the report's findings.

Page 5. Based on the discussion here, the OIG may wish to state that PROs should establish explicit policies to encourage complaint referrals from physicians, hospitals, or medical boards.

Page 6. The majority (59 percent) of PROs cited difficulties in making beneficiaries aware of the complaint process. It would be helpful to know what specific difficulties they encountered. If this was asked on the PRO survey, it would be useful to report the responses here.

Thank you again for the opportunity to comment. If you should have any questions, please contact Mary Jo Gibson in AARP's Public Policy Institute at (202) 434-3896 or Cheryl Matheis in Federal Affairs at 434-3774.

Sincerely,

  
John Rother  
Director, Legislation  
and Public Policy

**Coalition for Consumer Protection and Quality in Health Care Reform**  
1275 K Street, N.W., Suite 900 Washington, DC 20005  
(202)789-3606 Fax (202)842-1150

September 15, 1995

Ms. June Gibbs Brown  
Inspector General  
Department of Health and Human Services  
Cohen Building, Room 5250  
330 Independence Ave., S.W.  
Washington, D.C. 20201

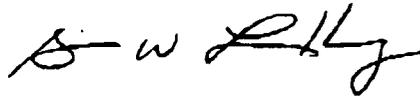
Dear Ms. Brown:

Thank you for the opportunity to review and comment on your draft inspection report, "The Beneficiary Complaint Process of the Medicare Peer Review Organizations." I am pleased to provide to you the comments of four of the Consumer Coalition's members, and I know that others in the Consumer Coalition have provided their comments to you independently.

Please keep our Coalition in mind to review and comment on other reports that you produce in the areas of health care consumer protection and quality. We would also be willing to assist with your studies in any other ways that you consider appropriate.

Thank you again for including us and for your efforts to improve these important health care programs.

Sincerely,



Brian W. Lindberg  
Executive Director



TO: Brian Lindberg  
FROM: Geraldine Dallek, Center for Health Care Rights  
RE: The OIG Draft Report on The Beneficiary Complaint Process of the Medicare Peer Review Organizations  
DATE: September 5, 1995

---

The OIG report provides a thoughtful critique of the PRO complaint system and offers some critically important suggestions for reform of the system. Given the likelihood of some basic reform in the Medicare program and the potential for substantial increased Medicare enrollment in managed care, the report is especially timely.

What follows are some specific comments on the report and additional suggestions for improving the PRO complaint process.

#### **NEED FOR A PRO PROCESS RESPONSIVE TO BENEFICIARY COMPLAINTS**

The Center for Health Care Rights (CHCR) provides education, counseling and legal services to over 15,000 Medicare beneficiaries annually. With the exception of hospital discharge cases, we refer few Medicare beneficiaries to our PRO (CMRI). The reasons are two-fold:

(1) The Inability of PROs to Provide Complainants with Information on the Disposition of Their Complaints

As the OIG notes, the lack of a meaningful PRO response to beneficiaries' complaints is incredibly frustrating. Indeed, it is such an impediment to the review process, that I believe unless it is changed, PROs will never be able to effectively represent Medicare beneficiaries. Nor will PROs, regardless of outreach efforts, be sent more than a trickle of complaints.

(2) The Length of the Review Process and Inability of PROs to Respond in a Timely Manner to Emergency Cases

As the OIG also noted, the review process is too lengthy. I am especially concerned about the lack of formal procedures for the PRO to investigate emergency cases where delays could result in serious harm to a beneficiary. Again, with the exception of hospital discharge cases, CHCR does not view a complaint to the PRO as an effective way to obtain redress for our client concerns, especially those relating to denials of care by HMOs.

### **NEED FOR GREATER SPECIFICITY ON THE COMPLAINT PROCESS**

The OIG report contains a number of recommendations for changes in the PRO complaint system, including specific requirements detailing to the complainant what it did to investigate the complaint, the outcome of the investigation and any action taken by the PRO.

In addition, I believe the OIG's report should include recommendations to HCFA on substantive additional changes in the complaint system including: recommended time frames for handling complaints, protocols for who investigates complaints; standards for what types of complaints should be handled by the PROs; standards on how complaints should be investigated; and, as discussed below, reporting of outcomes of complaint investigations to the public.

Currently, the PROs do not seem to investigate cases when care is denied, focusing instead on the delivery of poor quality of care. We believe that denials of appropriate care are, by definition, poor quality care and should be investigated by

### **LACK OF COORDINATION BETWEEN THE PROS, HCFA AND STATE REGULATORY AGENCIES**

The California Department of Corporations (DOC), which regulates HMOs in the state, will soon inaugurate a hot line for HMO consumer complaints. DOC has told CHCR that it plans to refer all Medicare HMO complaints to HCFA Region 9.

We do not know how HCFA will handle the large number of expected calls. HCFA and CMRI need to establish protocols for handling these complaints and sharing complaint information.

OIG should include in its report specific recommendations for ways that the PROs, HCFA and state agencies should coordinate the handling of beneficiary complaints and share complaint information.

### **LACK OF PUBLISHED PRO COMPLAINT DATA**

In addition to informing individual complainants of the outcome of the PRO's investigation of their complaints, PROs should be given authority to publish complaint data on an annual basis, including:

- ◆ The number of complaints by provider type (FFS, Physician, Hospital, HMO, Home Health Agency) and types of complaints (e.g., denials of care, poor quality care, etc.).

- ◆ Outcome of complaints by provider type;
- ◆ The names of institutional providers ( HMOs and when applicable, contracting provider groups , hospitals, home health agencies, etc.) for whom complaints were found to be, following an investigation, justifiable.

### **OUTREACH THROUGH GROUPS REPRESENTING MEDICARE BENEFICIARIES**

All states have federally funded ICA programs which could be a potential source of beneficiary complaints. A number of other organizations also represent the interest of Medicare beneficiaries. However, for the reasons stated above and a sense among some beneficiary groups that PROs have not, in the past, been responsive to beneficiary concerns, PROs will have to make a special effort to gain the trust of some of these organizations.

I believe that complaints from beneficiaries can be an effective source of monitoring quality of care. However, heavy reliance on complaints will not produce an effective quality monitoring system unless the entire PRO complaint system is changed to meet beneficiary needs.

Thank you for the opportunity to comment on the OIG's draft report.

**NATIONAL SENIOR CITIZENS LAW CENTER**  
1813 H STREET, N.W., SUITE 700  
WASHINGTON, D.C. 20006

TELEPHONE: (202) 887-5280 FACSIMILE (202) 785-6792

WASHINGTON, D C  
BURTON D. FRETZ  
EXECUTIVE DIRECTOR

September 14, 1995

Brian Lindberg  
Executive Director  
Coalition on Consumer Protection  
and Quality in Health Care Reform  
1275 K Street, N.W. , Suite 900  
Washington, DC 20005

Re: Comments on OIG Report on Beneficiary Complaint Process of the  
Medicare Peer Review Organizations

Dear Brian:

Thank you for the opportunity to submit comments on behalf of the National Senior Citizens Law Center (NSCLC). Over the years, NSCLC has been involved in numerous matters involving quality of care issues and Peer Review Organization (PRO) review, particularly issues of premature hospital discharges. For the most part, we have found the PRO review process to be unsympathetic to beneficiaries and the process of obtaining review cumbersome, even when working through an experienced advocate. In addition, the lack of a detailed and substantive response to beneficiaries complaints has impeded our ability to advocate on behalf of our clients.

1. As a general matter, there is still a question among beneficiary advocates about whether the PRO process should be maintained as it relates to beneficiary coverage and quality issues. Some advocates are of the opinion that the process delays meaningful review before a hearing officer, and administrative law judge review, etc, as appropriate.
2. Hospital notices explaining PRO review procedures have improved over the years. Nonetheless, beneficiaries do not always receive these notices in a timely fashion, nor do they always receive sufficient instruction from hospital staff about the importance of these notices.
3. We applaud the notion of expanding PRO outreach efforts in terms of publicity about the PRO review process. We would be happy to work with the

NATIONAL SENIOR CITIZENS LAW CENTER

Brian Lindberg  
Page 2  
September 14, 1995

Health Care Financing Administration (HCFA), the PRO community, and others in exploring ways of reaching Medicare beneficiaries to tell them about the role and function and value of the PRO process as it is improved.

4. We agree that the low number of beneficiary complaints being filed with the PRO is a problem. The problem is a function of poor outreach, bad beneficiary experiences with the PRO system, and ineffective notice systems within hospitals. We have long suggested that hospitals be required to play a larger role in the patient education and outreach efforts about the PRO process. We suggest the use of notice boards in hospitals, presenting information about the PRO process at several points during a patient's stay in the hospital, and the use of patient advocates or a hospital ombudsman to augment education and outreach efforts.

5. Hospital utilization review committees should involve Medicare beneficiaries in all aspects of utilization questions. This would give beneficiaries greater access to the PRO process and increase beneficiary comfort levels in using the PRO review process.

6. It would also be useful if PROs were required to publish and make available to the beneficiary community statistical information about the number, nature, and disposition of complaints received. This information could be made available in hospitals, at senior centers, and to individuals upon request.

Again, thank you for the opportunity to comment.

Sincerely,



Alfred J. Chiplin, Jr.  
Staff Attorney

CENTER FOR MEDICARE ADVOCACY, INC.  
c/o SOUTHERN ARIZONA LEGAL AID  
64 E. BROADWAY BLVD.  
TUCSON, ARIZONA 85701-1720  
(602) 623-9465 1 (800) 248-8789  
FAX (602) 620-0443

ATTORNEYS  
CHARLES C. HULIN  
JUDITH STEIN HULIN  
BRAD S. PLESANI  
WALTER R. KEENAN  
USHMA PATEL-NARVIL

LEGAL ASSISTANTS  
ELIZABETH W. DYLIK  
SUSAN L. KRUPINSKI  
CHERYL S. HALL

COMPUTER SPECIALIST  
LARRY S. GLATZ

OF COUNSEL  
SALLY HART WILSON

September 7, 1995

Brian Lindberg  
Executive Director  
Coalition for Consumer Protection  
and Quality for Health Care Reform  
1275 K Street, N.W.  
Washington, D.C. 20005

Dear Brian:

Thank you for giving me the opportunity to comment on the OIG draft inspection report, "The Beneficiary Complaint Process of the Medicare Peer Review Organizations." My comments on the draft report, in no particular order, are as follows:

1. The OIG and PROs are correct in concluding that random reviews of sample medical records were an ineffective way to improve quality of care, and that responding to beneficiary complaints is a far better way to uncover problem areas. (Why did it take them so long to figure this out?)

2. We should urge the PROs to devote much more attention to investigating instances of underservice by HMOs, as this is the area in which Medicare beneficiary advocates find the greatest problems.

3. Closer links should be developed between PROs and Medicare beneficiary advocates. Until now, many PROs have been quite unresponsive to beneficiary advocates in their regions. Greater contact would help increase the number of complaints they receive and sensitize them to beneficiary interests.

4. PROs should not rely only on medical records in investigating beneficiary complaints. Medical records do not reliably document instances of poor quality medical care (after all, who creates the records?)... Medical records are even less likely to document situations where the problem was that not enough medical care was provided, which is the most common problem where HMOs are involved.

Brian Lindberg  
September 7, 1995  
Page 2

5. The report's statistic that PROs have found confirmed quality of care problems in 10 to 15 % of complaints is shockingly low. Beneficiaries rarely go to the trouble of lodging complaints that are not justified. This low confirmation rate may result from a number of factors: PROs are generally too solicitous of providers; PROs can not obtain all of the relevant facts from medical records; PRO quality of care protocols in many cases simply do not measure underservice. Beneficiaries will not bother lodging complaints unless the resulting investigations are more balanced.

6. Many observers have noted that PROs do not seem to be the appropriate agencies to monitor quality of care, since they are also entrusted by HCFA with the job of performing hospital utilization review. This inconsistency in their two hats should be removed.

7. HCFA should work on developing a penalty system that gives beneficiaries an incentive for referring their problems to the PROs--e.g., monetary fines levied in response to deficiencies that are found in health care.

8. PROs should work with other agencies that review medical quality such as licensing boards and HMO regulatory agencies to create stronger incentives for providers to provide adequate, quality care.

I am sorry to have been slow in getting these comments to you. Please let me know if I can be of further assistance.

Very truly yours,

  
Sally Hart Wilson  
Attorney at Law

SHW:md



# Citizen Advocacy Center

*A Training, Research, and Support Network for Public  
Members of Health Care Regulatory and Governing Boards*

September 14, 1995

Mr. Brian Lindberg, Executive Director  
Coalition for Consumer Protection and  
Quality for Health Care Reform  
1275 K Street, NW, Suite 900  
Washington, DC 20005

Dear Brian:

Thank you for asking CAC to comment on the OIG draft inspection report entitled, "The Beneficiary Complaint Process of the Medicare Peer Review Organizations (PROs)." As you know, CAC is a unique support program for the thousands of public members who serve on health care regulatory boards and governing bodies as representatives of the consumer interest. Whether appointed by governors to serve on regulatory or other health policy boards or selected by private sector institutions and agencies to serve on boards or advisory panels, public members are typically in the minority and are usually without the resources and technical support available to their counterparts from professional and business communities. CAC is a not-for-profit 501(c)(3) organization created to serve the public interest by providing research, training, technical support, and networking opportunities to help public members make their contributions informed, effective, and significant.

One of our networks under the CAC umbrella is PRONET, made up of the Medicare beneficiary members who serve on the boards of directors of all PROs. At PRONET's annual meeting in Salt Lake City, Utah, on September 28, 1995, these beneficiary members will be discussing the draft report and most likely issuing their own comments on it. However, because of the deadline you told us you were operating under, we wanted to give you the comments of CAC. Please understand that the CAC comments may or may not be similar to those that PRONET will make later this month. I will send you a copy of whatever results from the PRONET meeting.

We appreciate your asking our views. As one of the members of your coalition, we are pleased to respond, since we closely observe the PRO program.

The OIG makes three findings, and offers three recommendations. We would like to comment briefly on each.

**OIG Finding #1.**        **Complaints to PROs can be an important source for identifying quality-of-care problems.**

**Comment.** We agree. As you know, we also are deeply involved with the operation of state health licensing boards. Both the PROs and the licensing boards can do a much better job of protecting the public health and safety if they have direct access to the users of health services. While PROs can and do have the authority to review medical records of patients, that is not the same as hearing from patients who have had an adverse experience. Granted, some complaints are frivolous, and some do not really fall within the PRO's authority. Nevertheless, enough of them do allege actions or inactions that should be investigated and, if substantiated, dealt with in an appropriate manner.

**OIG Finding #2.**        **Medicare beneficiaries are often unaware of their opportunities to complain to PROs about the quality of their medical care.**

**Comment.** The OIG finding does not surprise us. Most studies show that the public is uninformed as to the existence of PROs and licensing board and the authorities under which they operate. This lack of awareness is a problem that cannot be corrected overnight, but the effort should be made. If one examines the budgets of most PROs, one will find precious few dollars allocated to beneficiary education and outreach. CAC did a study a while back (copy enclosed) that examined PRO outreach programs. As you will see, some PROs spend as little as \$5,000 a year on outreach (Table 25, page 72). Almost half the PROs (24) had outreach budgets of between \$5,000 and \$50,000. Not a single PRO had an outreach budget of over \$100,000. Some PROs have developed imaginative outreach programs to do a better job of beneficiary education. Furthermore, the Fifth Scope of Work in HCFA's contracts with PROs elevates outreach to a higher priority than it has had in the past. But, until there is a much larger financial commitment, these programs are unlikely to overcome the lack of knowledge found by the OIG and others.

**OIG Finding #3.**        **As it works now, the complaint process has some flaws that undermine its effectiveness:**

- o        **Lack of substantive response**
- o        **Few complaints**
- o        **Lengthy process**

**Comment.** Again, the OIG finding is disturbing but not surprising. If few beneficiaries know that they have a right to complain (Finding #2), then of course there won't be very many complaints registered. If those who do complain get a non-substantive response, and if that non-substantive response takes an unduly long

time to arrive, then the complainant is unlikely to ever complain again, and is likely to discourage friends and relatives from registering complaints of their own.

In summary, the OIG finds that complaints can be an important source of information to help PROs identify quality of care problems, but very few beneficiaries know about the complaint process, and those few who do use the system find it seriously flawed and non responsive.

The OIG offers three solutions, in the form of recommendations, namely:

- The HCFA should work with PROs to identify cost-effective ways to correct the flaws in the complaint process. Toward that end, HCFA should:
  - o Require PROs to respond substantively to the complainant. This is the standard to which the Joint Commission on the Accreditation of Health Care Organizations holds hospitals accountable. The HCFA should give this the highest priority.
  - o Identify cost-effective ways to enhance Medicare beneficiaries' awareness of PROs and the complaint process.
  - o Streamline the complaint process.

We support each of these recommendations, and find them on target. In addition, we would add a recommendation that PROs not only be allowed more flexibility in conducting outreach activities, but that these activities be allocated higher levels of funding.

We would also recommend that as part of streamlining the complaint process, PROs be given specific deadlines for each phase of complaint handling -- for example, 14 days to acknowledge receipt of the complaint; 30 days to complete a preliminary investigation; 60 additional days to complete a fuller investigation -- and be required to justify each instance where the time limits were exceeded.

Finally, we believe that HCFA should regularly compile complaint handling statistics from all PROs and issue an annual report describing their substance and their resolution. A good model would be the California Board of Medicine's Annual Report.

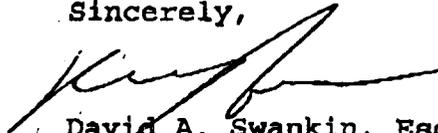
CAC is aware that PROs have moved away from case-by-case review and toward pattern analysis. However, PROs still retain authority to receive, investigate, and act upon complaints. So long as they have this authority, PROs should be expected to exercise it responsibly. Otherwise, PROs leave complainants with

a false confidence that their complaints are being handled appropriately.

There are really only two viable choices; either correct the deficiencies documented in the OIG report, or remove from PROs the responsibility for handling complaints, reduce their budgets accordingly, and direct the funds to organizations better equipped or more willing to handle complaints effectively, promptly, and appropriately.

Again, we appreciate this opportunity to comment.

Sincerely,



David A. Swankin, Esq.  
President

# APPENDIX F

---

## NOTES

1. The Institute of Medicine, *Medicare: A Strategy for Quality Assurance* (Washington, D.C.: National Academy Press, 1990).
2. Hebbel and McMullan to Executive Directors, Peer Review Organizations, 20 December 1994, Health Care Financing Administration, Baltimore, MD.
3. Other instances in which HCFA requires the PROs to conduct case reviews include hospital-issued notices of noncoverage, referrals from HCFA or the fiscal intermediary, adjustments to higher-weighted DRGs, and other limited instances.
4. The PROs must review complaints about the quality of care in the following settings: fee-for-service inpatient hospitals; fee-for-service freestanding ambulatory surgical centers; fee-for-service home health agencies, skilled nursing facilities, hospital outpatient areas, and emergency rooms; risk-sharing health maintenance organizations; and services received through cost-based health maintenance organizations. The PRO review is mandatory for written, quality-related complaints about services received in a physician's office when the physician is a part of a health maintenance organization in which the beneficiary is enrolled.
5. See 42 CFR 476.
6. The Health Care Financing Administration defines beneficiary protection under HCQIP as comprising four key elements:
  1. **A quality surveillance system.** The HCFA defines surveillance as "an ongoing epidemiologic strategy to identify quality problems, structured by hypotheses about what the problems are." The HCFA further defines the aims of the quality surveillance system as targeting and supporting quality improvement projects by "finding and fixing unacceptable patterns as diverse as high rates of medication errors, high rates of unnecessary right heart catheterization, and systematic delays in providing antibiotics to patients with infections."
  2. **Strategies to identify and intervene in instances of incompetent and impaired physicians and providers.** According to HCFA, the HCQIP employs two methods to effectively identify and root out incompetence. First, physicians and hospitals who fail to participate in and improve as a result of projects will become "increasingly isolated and obvious." It states that "data collected in projects and shared on a confidential basis will become persuasive evidence for implicit peer pressure and for exclusion if that becomes necessary." Second, PROs will become more aggressive in soliciting and investigating complaints, "including

strengthened liaison with licensing and certifying agencies and existing local consumer protection and advocacy programs."

**3. A more comprehensive and informative approach toward resolving beneficiary complaints concerning quality issues.** The HCFA states that "traditional peer review of individual cases will remain a key tool for investigating complaints." In addition, HCFA is revising its regulations to "provide more thorough and sensitive follow-up to beneficiary complaints." According to HCFA, the new rules and procedures for complaints "will permit (and HCFA will require) PROs to explain health care events to beneficiaries to promote understanding and encourage conflict resolution."

**4. Enhanced beneficiary information activities.** The HCFA is currently "exploring ways to improve educational and informational activities to ensure that beneficiaries are fully aware of their rights and opportunities under Medicare, including the right to have complaints about poor quality medical care investigated by the PROs."

(Gagel to Vladeck, 3 May 1994, "Beneficiary Protection Under the Health Care Quality Improvement Program (HCQIP)--DECISION," Health Standards and Quality Bureau of the Health Care Financing Administration, Baltimore, MD.)

7. Health Care Financing Administration, "The Successful PRO in 5 Years," Baltimore, MD, November 8, 1994.

8. This is based on our analysis of data representing 11 PROs' beneficiary complaints and the number of cases with at least 1 confirmed quality-of-care problem. Each case can have multiple quality-of-care problems. For 20 PROs in our sample, we had number of individual problems. When we calculate the rate for those 20 PROs, the result is within the range of the case results presented: at least 10.5 percent to as many as 17.3 percent.

9. This PRO, from the low-population stratum, reported having received 13 complaints under the fourth contract at the time of our survey.

10. The PROs' responses to these systems issues also varied, and included action plans, HCQIP projects, and consideration of sanction, among others.

11. Gagel to Vladeck, 3 May 1994.

12. We asked the PROs how many complaints that triggered a case review were also referred elsewhere and listed the following choices: FI/carrier, managed care institution, hospital, HCFA project officer, survey and certification agency, and other. Because a PRO could have referred a single complaint more than once, we present both the most conservative interpretation of joint referrals (16.7 percent) and the most liberal (28.9 percent).

13. Because the HCFA project officer is likely to refer the complaint again, for example to the appropriate survey and certification agency, the percentages shown may be under-reported.

14. Thirteen of the 22 PROs reported having received referrals from physicians during the fourth contract period. Nine of these PROs reported having received either a small number or between 1 and 4 such referrals; 1 reported having received 6; and 2, 10 or more. One PRO did not offer an estimate.

Eight PROs reported having received referrals from hospitals. Those who offered an estimate reported having received between one and four referrals.

Six PROs reported having received referrals from State medical licensure boards. Those who offered an estimate reported having received one or two, or a few.

15. When we asked the PROs to identify two outreach activities leading to the most complaints, half the PROs identified local presentations.

16. Of the 13 PROs that judged reaching beneficiaries a major barrier to a more effective complaint process, 4 were from the low-population stratum.

17. Five of the 22 PROs in our sample noted that, in some cases, the response to the request for consent was pending.

18. The 5 PROs in the low-population stratum gained consent 84 percent overall compared to 43 percent for the 17 PROs in the high-population stratum. The PROs in the low-population stratum gained consent in 25 percent of the complaints involving confirmed physician quality-of-care problems (3 of 12 such complaints) compared with 13 percent for the high-population PROs (22 of 176 such complaints).

19. The 7 cycle-1 PROs in our sample received between 31 and 141 complaints per million beneficiaries, a spread of 110 per million; the 7 cycle-2 PROs, between 50 and 164, a spread of 114 per million; and the 8 cycle-3 PROs, between 8 and 125, a spread of 117 per million.

20. Miscellaneous reviews account for 19.2 percent of the review caseload. Other mandatory reviews, such as hospital-issued notices of noncoverage, account for 8.4 percent. After October 1995, the PROs' review caseloads will include complaints and other mandatory reviews.

21. Health Care Financing Administration, "Strategic Plan," Baltimore, MD, 1994, p.3.

22. Ibid, p. 17.